

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2002 list were published in the Federal Register in September 2002.

Supplemental Approvals

NADA Number: 141-189

This supplemental application provides for the additional indication for the treatment of existing larval and adult hookworm (*Uncinaria stenocephala*) infections.

Trade Name: ProHeart® 6 Sustained Release Injectable for Dogs
Ingredients: Moxidectin
Sponsor: Fort Dodge Animal Health, Division of American Home Products Corp.
Approval Date: June 13, 2002
Status: Prescription only
Route: Subcutaneous
Species: Dogs (6 months and older)
Drug Form: Microspheres (sterile for reconstitution)
Concentration: 3.4 milligrams per milliliter
Indications: For the prevention of heartworm disease caused by *Dirofilaria immitis* in dogs 6 months of age and older. For the treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.
Patent Number: 4,916,154
Exclusivity: 3 years

Expiration Date: April 10, 2007

21CFR 522.1451

Suitability Petition Action

Number: 02P-0396/CP1
Sponsor: Intervet, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Eqvalan® Paste 1.87%, Merial Ltd., NADA 134-314 by the following characteristics: The generic product will consist of a different dosage form ('soft-chew') and strength (0.45%) from the pioneer.
Action: Filed September 5, 2002.

Number: 00P-1486/PRC1
Sponsor: Equi Aid Products, Inc.
Petition: Request permission for reconsideration to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form ('chewable') and strength (22.7 milligrams per 'chewable') from the pioneer.
Action: Approved September 18, 2002.

Number: 02P-0416/CP1
Sponsor: Highland VetPharma, LLC
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, ivermectin (Eqvalan®), Merial Ltd., NADA 134-314 by the following characteristics: the generic product will consist of a different dosage form (palatable chewable bolus) and strength (22.75 milligrams per 'chewable') from the pioneer.
Action: Filed on September 18, 2002.